IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INFORLIFE SA and WG CRITICAL CARE, LLC, Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES, LTD. and SUN PHARMACEUTICAL INDUSTRIES, INC., Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs InfoRLife SA ("InfoRLife") and WG Critical Care, LLC ("WG Critical Care," and collectively with InfoRLife, "Plaintiffs") file this Complaint for patent infringement against Defendants Sun Pharmaceutical Industries, Ltd. ("Sun Ltd.") and Sun Pharmaceutical Industries, Inc. ("Sun Inc.," and collectively with Sun Ltd., "Sun"), and by their attorneys, hereby allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202, that arises out of Sun's submission of an amendment to a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import midazolam in 0.9% sodium chloride (100 mg/100 ml) solution, for intravenous use ("Sun's NDA Product"), a generic version of InfoRLife's midazolam in 0.9% sodium chloride (50 mg/50 ml and 100 mg/100 ml) solution,

for intravenous use, prior to the expiration of U.S. Patent No. 10,966,990 (the "'990 Patent" or "the patent-in-suit").

2. Sun Ltd. notified InfoRLife by letter dated October 29, 2021 ("Sun's Notice Letter") that it had submitted to the FDA an amendment to NDA No. 212518 ("Sun's NDA"), seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of Sun's NDA Product prior to the expiration of the patent-in-suit.

PARTIES

3. Plaintiff InfoRLife is a company organized and existing under the laws of Switzerland, with its principal place of business at Casai, 7748 Campasico, Switzerland. InfoRLife is the owner by assignment of the '990 Patent. InfoRLife is the holder of New Drug Application ("NDA") No. 211844 for the sale of midazolam in 0.9% sodium chloride (50 mg/50 ml and 100 mg/100 ml) solution, for intravenous use, which has been approved by the FDA.

4. Plaintiff WG Critical Care is a limited liability company organized and existing under the laws of the State of New Jersey, having a principal place of business at 120 Route 17 North, Paramus, New Jersey 07652. WG Critical Care is the exclusive licensee of the '990 Patent.

5. Upon information and belief, defendant Sun Ltd. is a company organized and existing under the laws of the Republic of India with a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, India. On information and belief, Sun Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products through various operating subsidiaries, including Sun Inc.

6. Upon information and belief, defendant Sun Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2

Independence Way, Princeton, New Jersey 08540. On information and belief, Sun Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

7. Upon information and belief, Sun Inc. is a wholly owned subsidiary of Sun Ltd. and is controlled and/or dominated by Sun Ltd.

8. Upon information and belief, Sun Ltd. and Sun Inc. acted in concert to prepare and submit Sun's NDA to the FDA.

JURISDICTION

9. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

10. This Court has personal jurisdiction over each of Sun Ltd. and Sun Inc.

11. Sun Ltd. is subject to personal jurisdiction in Delaware because, among other things, Sun Ltd., itself and through its wholly-owned subsidiary Sun Inc., has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Sun Ltd., itself and through its wholly-owned subsidiary Sun Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Sun Ltd. is subject to personal jurisdiction in Delaware because, on information and belief, it controls Sun Inc., and therefore the activities of Sun Inc. in this jurisdiction can be attributed to Sun Ltd.

12. Sun Inc. is subject to personal jurisdiction in Delaware, because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that

it should reasonably anticipate being haled into court here. Upon information and belief, Sun Inc. is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Sun Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

13. Sun has previously used the process contemplated by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

14. Upon information and belief, Sun, with knowledge of the Hatch-Waxman Act process, directed Sun's Notice Letter to InfoRLife, and alleged in Sun's Notice Letter that the patent-in-suit is not infringed. Upon information and belief, Sun knowingly and deliberately challenged InfoRLife's patent rights, and knew when it did so that it was triggering the forty-five day period for InfoRLife to bring an action for patent infringement under the Hatch-Waxman Act.

15. Upon information and belief, if Sun's NDA is approved, Sun Ltd. and Sun Inc. will act in concert to directly or indirectly manufacture, market, sell, and/or distribute Sun's NDA Product within the United States, including in Delaware, consistent with Sun's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief,

Sun regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Sun's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Sun's NDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of InfoRLife's patent in the event that Sun's NDA Product is approved before the patent-in-suit expires.

16. Upon information and belief, Sun derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Sun and/or for which Sun is the named applicant on approved ANDAs. Upon information and belief, various products for which Sun is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

17. Upon information and belief, Sun Ltd. and Sun Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of general pharmaceutical products throughout the United States, including in Delaware, and including with respect to Sun's NDA Product. On information and belief, Sun Ltd. and Sun Inc. together participated in, assisted, and cooperated in the acts complained of herein.

18. In addition, this Court has personal jurisdiction over Sun because Sun has engaged in patent litigation concerning FDA-approved branded drug products in this district, does not

contest personal jurisdiction in this district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.,* Sun's Answer at ¶ 16, *Pfizer Inc., et al. v. Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries Inc.*, C.A. No. 21-285-CFC (D. Del. Mar. 22, 2021) (stating Sun did not contest personal jurisdiction for purposes of that specific action); Sun's Answer at 10–11, *Galderma Labs. L.P., et al. v. Sun Pharmaceutical Industries Ltd. et al.*, C.A. No. 18-1588-LPS (D. Del. Jan. 31, 2019) (asserting counterclaims); Complaint at 10–12, *Sun Pharma Global FZE and Sun Pharmaceutical Industries, Ltd. v. Teva Pharmaceuticals USA, Inc. et al*, C.A. No. 18-1552-RGA (D. Del. Oct. 9, 2018) (asserting claims); Sun's Answer at ¶ 12, *Pfizer Inc., et al. v. Micro Labs USA Inc., et al.*, C.A. No. 17-158-LPS (D. Del. July 11, 2018) (stating Sun did not contest personal jurisdiction for purposes of that specific action).

19. Alternatively, if Sun Ltd.'s connections with Delaware are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Sun Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Sun Ltd. in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

VENUE

20. Venue is proper in this district as to Sun Ltd. pursuant to 28 U.S.C. §§ 1391 because, *inter alia*, Sun Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

21. Venue is proper in this district as to Sun Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

22. Midazolam in 0.9% sodium chloride (50 mg/50 ml and 100 mg/100 ml) solution, for intravenous use, is a benzodiazepine indicated for continuous intravenous infusion for sedation of intubated and mechanically ventilated adult, pediatric, and neonatal patients as a component of anesthesia or during treatment in a critical care setting. InfoRLife sells these products in the United States pursuant to its NDA No. 211844.

23. In Sun's Notice Letter, Sun provided an Offer of Confidential Access to Application ("OCA") to InfoRLife to access certain information from Sun's NDA for the purpose of determining whether an infringement action can be brought. Plaintiffs' counsel obtained access to and reviewed relevant portions of Sun's NDA pursuant to the OCA.

24. Upon information and belief, Sun's NDA Product is a generic version of midazolam in 0.9% sodium chloride (100 mg/100 ml) solution, for intravenous use.

25. Plaintiffs are filing this Complaint within forty-five days of receipt of Sun's Notice Letter.

COUNT I – INFRINGEMENT OF THE '990 PATENT

26. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

27. The '990 Patent, entitled "Midazolam in Flexible Bags" (attached as Exhibit A), was duly and legally issued on April 6, 2021.

28. InfoRLife is the owner and assignee of the '990 Patent.

29. WG Critical Care holds an exclusive license to the '990 Patent for the commercial exploitation and sale of midazolam in 0.9% sodium chloride (50 mg/50 ml and 100 mg/100 ml) solution, for intravenous use.

30. In general, the claims of the '990 Patent are directed to a ready-to-use, aqueous midazolam solution in an intravenous laminated flexible plastic bag.

31. Plaintiffs' FDA-approved midazolam in 0.9% sodium chloride (50 mg/50 ml and 100 mg/100 ml) solution, for intravenous use, is covered by the '990 Patent, as recited in one or more claims of the '990 Patent, and the '990 Patent has been listed in connection with midazolam in 0.9% sodium chloride (50 mg/50 ml and 100 mg/100 ml) solution, for intravenous use, in the FDA's Orange Book.

32. In Sun's Notice Letter, Sun notified InfoRLife of the submission of Sun's NDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of Sun's NDA Product prior to the expiration of the '990 Patent.

33. In Sun's Notice Letter, Sun also notified InfoRLife that, as part of its NDA, Sun had filed certifications of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355 (b)(2)(A)(iv), with respect to the '990 Patent. On information and belief, Sun submitted its NDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) asserting that the '990 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's NDA Product.

34. According to Sun's Notice Letter, Sun's NDA Product is midazolam in 0.9% sodium chloride (100 mg/100 ml) solution, for intravenous use.

35. Upon information and belief, Sun's NDA Product and the use of Sun's NDA Product in accordance with its proposed labeling satisfies literally and/or under the doctrine of equivalents each of the limitations of at least claims 1-4, 6-9, and 11-13 of the '990 Patent.

36. As an example, claim 1 of the '990 Patent recites:

> A ready-to-use terminally sterilized, preservative-free aqueous midazolam solution in an intravenous laminated flexible plastic bag, comprising 0.25 to 1.5 mg/ml of midazolam, sufficient tonicity adjusting agent to provide an osmolality of from 260 and 320 mosm/kg and sufficient acid and optionally a base to provide a pH of from about 2.5 to 3.5 with the remainder water for injection;
>
> wherein:
>
> the tonicity adjusting agent comprises at least one selected from the group consisting of sodium chloride, potassium chloride and calcium chloride;
>
> the acid comprises hydrochloric acid;
>
> the base, if present, comprises sodium hydroxide; and
>
> the midazolam content after accelerated storage at 40° C. for six months is greater than 97%
>
> the intravenous laminated flexible plastic bag comprises from 3 to 7 layers and has an innermost layer comprises an ethylene-vinyl acetate coplymer [sic].

37. Upon information and belief, Sun's NDA Product and the use of Sun's NDA Product in accordance with its proposed labeling infringes at least claim 1 of the '990 Patent under the doctrine of equivalents.

38. Sun's submission of Sun's NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's NDA Product before the expiration of the '990 Patent was an act of infringement of the '990 Patent under 35 U.S.C. § 271(e)(2)(A).

39. Upon information and belief, Sun will engage in the manufacture, use, offer for sale, sale and/or importation of Sun's NDA Product immediately and imminently upon approval of its NDA.

40. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's NDA Product would infringe under the doctrine of equivalents one or more claims of the '990 Patent.

41. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's NDA Product in accordance with, and as directed by, its proposed labeling would infringe under the doctrine of equivalents one or more claims of the '990 Patent.

42. Sun was aware of the '990 Patent before it submitted its NDA to the FDA. Upon information and belief, Sun plans and intends to, and will, actively induce infringement of the '990 Patent when Sun's NDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun's activities will be done with knowledge of the '990 Patent and specific intent to infringe that patent.

43. Notwithstanding Sun's knowledge of the claims of the '990 Patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, and/or import Sun's NDA Product with its product labeling following FDA approval of Sun's NDA prior to the expiration of the '990 Patent.

44. The foregoing actions by Sun constitute and/or will constitute infringement of the '990 Patent and active inducement of infringement by others of the '990 Patent.

45. Upon information and belief, Sun has acted with full knowledge of the '990 Patent and without a reasonable basis for believing that it would not be liable for infringement of the '990 Patent, active inducement of infringement of the '990 Patent, and/or contribution to the infringement by others of the '990 Patent.

46. Plaintiffs will be substantially and irreparably damaged by infringement of the '990 Patent.

47. Unless Sun is enjoined from infringing the '990 Patent and actively inducing infringement of the '990 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '990 PATENT

48. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

49. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Sun on the other regarding Sun's infringement and active inducement of infringement of the '990 Patent.

50. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Sun's NDA Product with its proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the '990 Patent, will infringe and induce the infringement of the '990 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the patent-in-suit has been infringed under 35 U.S.C. § 271(e)(2) by Sun's submission to the FDA of Sun's NDA;

B. A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Sun's NDA Product, or any other drug product that infringes or the use of which infringes the patent-in-suit, be not earlier than the expiration dates of said patent, inclusive of any extension(s) and additional period(s) of exclusivity;

C. A preliminary and permanent injunction enjoining Sun, its officers and directors, and all persons acting in concert with Sun, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sun's NDA Product, or any other drug product covered by or whose use is covered by the patent-in-suit, prior to the

expiration of said patent, inclusive of any extension(s) and additional period(s) of exclusivity;

D. A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Sun's NDA Product, or any other drug product which is covered by or whose use is covered by the patent-in-suit, prior to the expiration of said patent, will infringe and induce the infringement of said patent;

E. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com

Attorneys for Plaintiffs

OF COUNSEL:

Steven Lieberman
Jennifer Nock
Caitlin M. Wilmot
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
607 14th Street, N.W., Suite 800
Washington, DC 20005
(202) 783-6040

December 10, 2021